

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 2, drawn to a method for inhibiting apoptosis of epidermal cells by increasing expression of SCCA-1 and/or SCCA-2 in epidermal cells.

Group 2, claim(s) 3-5, drawn to a method for testing skin by evaluating resistance to skin damage caused by ultraviolet irradiation of the skin, comprising: measuring the amounts of SCCA-1 and/or SCCA-2 in epidermal cells, and judging ultraviolet resistance of the skin to be weak in the case said amounts are decreased as compared with expression in epidermal cells.

Group 3, claim(s) 6, drawn to a method for screening drugs which enhance resistance to skin damage caused by ultraviolet irradiation of skin, comprising: selecting a drug which increases expression of SCCA-1 and/or SCCA-2 for use as a ultraviolet resistance enhancer.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

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The inventions listed in Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-3 appears to be SCCA-1 and/or SCCA-2 expression.

However, Takeda et al. (J. Invest. Derma. Jan. 2002, 118:147-154, IDS item) teaches measuring SCCA-1 and SCCA-2 expression in psoriatic skin, see page Abstract and Figs. 2-7.

Therefore, the technical feature linking the inventions of Groups 1-3 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Species Elections for Groups I-III

A. Claims 1, 3 and 6 are generic to the following disclosed patentably distinct species of SCCA molecule:

- 1) polynucleotide, as contemplated in the specification
- 2) polypeptide, as contemplated in the specification

B. Claims 1, 3 and 6 are generic to the following disclosed patentably distinct species of SCCA molecule examined:

- 1) SCCA-1
- 2) SCCA-2
- 3) SCCA-1 and SCCA-2

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The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

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petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Peter J Reddig/
Examiner, Art Unit 1642
/P. J. R./

/Karen A Canella/

Primary Examiner, Art Unit 1643